

REQUIREMENTS AND INSTRUCTIONS FOR FILING - WHOLESALE PRESCRIPTION DRUG DISTRIBUTORS

Visit our website at: www.hawaii.gov/dcca/areas/pvl

ACTIVITIES COVERED UNDER THIS LICENSE

- Handling, distributing, or storing of legend or prescription pharmaceuticals, controlled substances, medical gases, transfilling of medical gases, or supplies and devices that contain or are accompanied by legend/prescription drugs, to persons other than a consumer or patient.
- "Wholesale distributor" means any person or entity in this State engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; prescription drug repackagers; physicians; dentists; veterinarians; birth control and other clinics; individuals; hospitals; nursing homes and their providers; health maintenance organizations and other health care providers; and retail and hospital pharmacies that conduct wholesale distributions. The term "wholesale distributor" shall not include any carrier for hire or person or entity hired solely to transport prescription drugs. For purposes of this section, "manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug; and "prescription drug" means any human drug required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

APPLICATION IS REQUIRED WHEN

- A person or entity will be operating, maintaining, opening, storing, changing location, or establishing a wholesale prescription drug distribution within the State of Hawaii.
- Ownership changes.
- A person or entity will be operating, maintaining, opening, storing, or establishing a vendor-managed inventory arrangement ("consignment arrangement") within Hawaii.

Note: If the person or entity is licensed in its state of domicile, and does not have a facility, office, or vendor-managed inventory located in Hawaii, the person/entity is not required to obtain a wholesale drug distributor license.

CONTROLLED SUBSTANCES

Be advised that the State may have different substances listed in its schedules of controlled substances. You are required to register with the Department of Public Safety, Narcotics Enforcement Division, if you will be shipping controlled substances. For further information, contact:

Department of Public Safety
Narcotics Enforcement Division
3375 Koapaka St. STE D100
Honolulu, HI 96819

Phone: (808) 837-8470

APPLICATION FORM (ORIGINAL AND 1 COPY)

COMPLETE APPLICATION AND SUBMIT, THE ORIGINAL AND ONE COPY TO THE BOARD. Type or print legibly in dark ink. Failure to provide the requested information will delay the processing of your application. **On the application, provide the name and position of person or persons responsible for the distribution of drugs, and an outline of at least one year's experience in the handling, storage, manufacture, or distribution of prescribed drugs.**

SOCIAL SECURITY NUMBER

Your social security number is used to verify your identity for licensing purposes and for compliance with the below laws. **For a license to be issued you must provide your social security number or your application will be deemed deficient and will not be processed further.**

The following laws require that you furnish your social security number to our agency:

FEDERAL LAWS:

42 U.S.C.A. §666(a)(13) requires the social security number of any applicant for a professional license or occupational license be recorded on the application for license; and

If you are a licensed health care practitioner, **45 C.F.R., Part 61, Subpart B, §61.7** requires the social security number as part of the mandatory reporting we must do to the Healthcare Integrity and Protection Data Bank (HIPDB), of any final adverse licensing action against a licensed health care practitioner.

HAWAII REVISED STATUTES ("HRS"):

§576D-13(j), HRS requires the social security number of any applicant for a professional license or occupational license be recorded on the application for license; and

§436B-10(4) HRS which states that an applicant for license shall provide the applicant's social security number if the licensing authority is authorized by federal law to require the disclosure (and by the federal cites shown above, we are authorized to require the social security number).

**VERIFICATION OF
WORK EXPERIENCE**

Submit written verification from a third party (for example, letter from a former employer) to verify at least one (1) year of work experience for the person(s) who will be responsible for the distribution and handling of prescribed drugs.

MAP OF FACILITY

Attach two (2) copies of a map of the facility showing the storage area for drugs, the storage area for quarantined drugs, and the placement of the lighting, ventilation, and temperature control equipment. Schematic drawing will be accepted; need not be a blueprint nor to scale.

**WRITTEN POLICIES AND
PROCEDURES**

Attach two (2) copies of written policies and procedures for the receipt, security, storage, inventory, and distribution of prescription drugs (which shall include medical gases) including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. These written policies and procedures shall include a procedure:

- 1) For the receipt, security, storage, inventory and distribution of prescription drugs;
- 2) For identifying, recording, and reporting losses or thefts and correcting errors in inventories;
- 3) Whereby the oldest stock is distributed first;
- 4) For handling recalls and withdrawals of prescription drugs;
- 5) For handling return of outdated prescription drugs, its segregation and documentation of disposal; and
- 6) To ensure the handling of any crisis in the event of natural disasters or local, state, or national emergencies.

**ENTITY
REGISTRATION**

If the application is for a corporation, partnership, LLC, or LLP, submit the following proof to show that the entity is properly registered with the Business Registration Division (BREG), Department of Commerce & Consumer Affairs, State of Hawaii, P.O. Box 40, Honolulu, HI 96810.

If the corporation/partnership/LLC/LLP has been registered in this state for LESS THAN ONE (1) YEAR, **ATTACH** a "*filed-stamped*" copy of the document filed with BREG; or the same certificate mentioned below (copy acceptable).

If the corporation/partnership/LLC/LLP has been registered in this state for MORE THAN ONE (1) year, **ATTACH** a "*Certificate of Good Standing*" or "*Certificate of Qualification*" (copy acceptable).

TRADE NAME

If applicant will be using a trade name, **attach a current** "filed-stamp" copy of the "*Application for Registration of Trade Name*" approved by the Business Registration Division. You may contact them at (808) 586-2727.

INSPECTION REQUIRED

An inspection conducted by the Department of Health, Food and Drug Branch, on the minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drugs distribution records **shall be successfully completed before a license is issued**. A copy of the inspection report is attached indicating the items for which the applicant will be inspected. Any item deemed unsatisfactory by the Department of Health shall prevent the issuance of a license. We will forward a copy of your application to the Department of Health.

RELOCATION

If filing for the relocation of a wholesale prescription drug distribution, complete and submit the attached application in duplicate, map of the facility, written policies and procedures, and the non-refundable application fee of \$100.

**NEW LICENSE-BUSINESS
FORMERLY OWNED BY
SOMEONE ELSE**

Attach a letter of verification from the former owner that the business (facility) has been bought and the effective date.

FEES

A license will be issued upon fulfillment of the above requirements, passing an inspection of the facility, approval by the board and the receipt of the appropriate *fees* due.

Make check payable to *COMMERCE & CONSUMER AFFAIRS for the applicable fees:*

If applying for license in an EVEN-NUMBERED year, pay\$295
 (*Application fee-\$100, License-\$50, Compliance Resolution Fund-\$70, 1/2 renewal-\$75).

If applying for license in an ODD-NUMBERED year, pay \$185**
 (*Application fee-\$100, License-\$50, Compliance Resolution Fund-\$35).

If applying for Relocation, pay \$100
****Application fee-\$100 (license fee not required).***

* Application fee is non-refundable.
 ** ALL licenses expire on December 31, ODD-NUMBERED years and are subject to renewal regardless of license issuance date.

NOTE: *One of the numerous legal requirements that you must meet in order for your new license to be issued is the payment of fees as set forth in this application. You may be sent a license certificate before the payment you sent us for your required fees is honored by your bank. If your payment is dishonored, you will have failed to pay the required licensing fee and your license will not be valid, and you **may not** do business under that license. Also, a \$25.00 service charge shall be assessed for payments that are dishonored for any reason.*

If denied the license you are applying for, you may be entitled to a hearing as provided by Title 16, Chapter 201, Hawaii Administrative Rules, and/or Chapter 91, Hawaii Revised Statutes. Your written request for a hearing must be directed to the agency that denied your application, and must be made within 60 days of notification that your application for a license has been denied.

ADDRESS OF BOARD

Mail all required items to: Deliver to office location at:

Board of Pharmacy 335 Merchant St., Room 301
 DCCA, PVL Licensing Branch or Honolulu, HI 96813
 P.O. Box 3469
 Honolulu, HI 96801

Phone: (808) 586-3000

Toll free voice access numbers for the neighbor islands:

Kauai - 274-3141 Ext. 6-3000
 Maui - 984-2400 Ext. 6-3000
 Hawaii - 974-4000 Ext. 6-3000
 Molokai - 1-800-468-4644 Ext. 6-3000
 Lanai - 1-800-468-4644 Ext. 6-3000

LAWS & RULES PUBLICATIONS

Copies are available by submitting a written request to: Board of Pharmacy, Department of Commerce & Consumer Affairs, P.O. Box 3469, Honolulu, HI 96801.

1. Chapter 461, Hawaii Revised Statutes; Pharmacists & Pharmacies
2. Title 16, Chapter 95, Hawaii Administrative Rules, Pharmacists & Pharmacies
3. Chapter 329, HRS, Uniform Controlled Substances Act
4. Chapter 328, HRS, Food, Drugs and Cosmetics
5. Chapter 436B, HRS, Professional and Vocational Licensing Law

The laws and rules are also available on our website at: www.hawaii.gov/dcca/areas/pvl. Click on "Pharmacy". Then click on "Statute/Rule Chapter".

APPLICATION STATUS

It is the responsibility of the applicant to arrange for submission of all required documentation for timely completion of the application. Applicants may contact the Department of Commerce & Consumer Affairs periodically to monitor the status of their file with regard to receipt of supporting documents.

BIENNIAL RENEWAL

All licenses, regardless of issuance date, are subject to renewal on or before December 31, of each ODD-NUMBERED year.

The failure to timely renew a license, including payment of fees shall cause the license to be automatically forfeited. A license which has been forfeited may be restored within three (3) years after the date of forfeiture upon compliance with the licensing renewal requirements. After 3 years, a new application for license shall be required.

ABANDONED APPLICATIONS

Pursuant to HRS §436B-9 your application shall be considered abandoned and shall be destroyed if you fail to provide evidence of continued efforts to complete the licensing process for two consecutive years. The failure to provide evidence of continued efforts includes but is not limited to: (1) failure to submit any required information and documents requested by the licensing authority within two consecutive years from the last date the documents and information were requested, or (2) failure to complete any additional requirements for licensure that remain after approval of your application, such as attempting to complete an exam requirement, within two consecutive years from the date your application was approved, or (3) failure to provide the licensing authority with any written communication during two consecutive years indicating that you are attempting to complete the licensing process. If an application is deemed abandoned the applicant shall be required to reapply for licensure and comply with the licensing requirements in effect at the time of the reapplication.

APPLICATION FOR LICENSE - WHOLESALE PRESCRIPTION FOR RELOCATION OF BUSINESS DRUG DISTRIBUTOR

Type or print legibly in **black ink**.

Circle type of BUSINESS ENTITY:

INDIVIDUAL (Sole Owner) CORPORATION PARTNERSHIP
LIMITED LIABILITY CO. (LLC) LIMITED LIABILITY PARTNERSHIP (LLP)

Name of Applicant (*First-Middle-LAST; or name of corporation, partnership, LLC or LLP*):

Trade Name (if used):

Hawaii Location (include suite no., city, state & zip code):

Mailing Address (if different from location):

Website Address:

E-Mail Address:

Social Security No. (individual)

Business Phone No.

()

FOR OFFICE USE ONLY

PWD CHECKOUT

[] Fees: \$295 / \$185 / \$100 [] BREGS
[] Policy & Procedure [] Map of Facility
[] Verif of work experience

Date Routed to Dept. of Health

Pre-Assigned No.

PWD-

Effective Date:

License No.

PWD-

☐ Relocation

Check the type of application being made:

[] NEW LICENSE. Business NOT owned by anyone else before.

[] NEW LICENSE. Business formerly owned by someone else.
(**Attach** letter of sale).

License number of former owner: _____

[] **RELOCATION**. Same owner but in a different location.

License No: PWD- _____

Is the premises ready for inspection?

YES

NO

If no, when will it be ready? _____

Provide name and position of person or persons responsible for the distribution of drugs. **Attach** an outline of at least one year of experience in the handling, storage, manufacture, or distribution of prescription drugs. **Attach** written verification from third-party. (If additional space is required, attach a separate sheet)

| Name | Position | | | |
|------|----------|--|-----|----|
| | | Have you attached verification of work experience? | YES | NO |
| | | Have you attached verification of work experience? | YES | NO |
| | | Have you attached verification of work experience? | YES | NO |

The following questions pertain to the applicant and any persons (pharmacist, officers, directors, managers, partners, etc.) responsible for the distribution of drugs. Circle your answers and attach pertinent documentation.

- Have any of the applicants and/or persons responsible for the distribution of drugs had any:
 - Convictions relating to the distribution of drugs (including samples)? YES NO
 - Felony convictions? YES NO
 - Suspensions or revocations of licensure for the manufacture or distribution of drugs by federal, state, or local laws, of any license currently or previously held by the applicant or persons responsible for the distribution of drugs in any state the applicant is conducting business? YES NO

If "Yes", list, explain, and **attach** copies of court documents on the date, place, violation of each conviction and fulfillment of the conditions of each sentence or the board's documents including Board's Final Order and current status.
- Are you a U.S. citizen, a U.S. national, or an alien authorized to work in the United States?.....YES NO
- List all Parent or Subsidiary companies, if any: _____.
- If applicant is a corporation, partnership, LLC or LLP, is verification attached to attest that the entity is properly registered with the Business Registration Division (BREG), Department of Commerce and Consumer Affairs, State of Hawaii?YES NO

(Continued on Back)

FILE IN DUPLICATE

(Original and one copy)

App.....496.....\$100
Lic..... 499 \$ 50
CRF..... 497 \$35/70
½ Ren 490 \$ 75
Service Charge BCF \$ 25

Name of Applicant: _____

| RESIDENCE ADDRESSES | Name | Social Security No. | Residence Address | Phone No. |
|---------------------|--------------------------------------|---------------------|-------------------|-----------|
| | Sole Owner | | | |
| | President, Partner, or Director | | | |
| | Vice-President, Partner, or Director | | | |
| | Secretary, Partner, or Director | | | |
| | Treasurer, Partner, or Director | | | |

Business Entities Applicant will serve: Type of Products to be handled and distributed by applicant:

- ☐ Pharmacies
☐ Practitioners
☐ Hospitals
☐ Wholesale/Distributors
☐ Other (list)
- ☐ Legend pharmaceuticals, supplies or devices
☐ Controlled substances
☐ Medical gases only

Are the written policies and procedures for the receipt, security, storage, inventory and distribution of prescription drugs including procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories attached? ☐ Yes ☐ No

If no, give a date when it will be available: _____.

(Note: An inspection with the Department of Health will not be scheduled until this and all other requirements are met.)

Affidavit of Applicant:

I certify that the statements, answers and representations made in this application and the documents attached are true and correct. I understand that misrepresentation is grounds for refusal or subsequent revocation of license and is a misdemeanor (*Section 710-1017, Sections 436B-19 and 461-21, Hawaii Revised Statutes*).

I further certify that the wholesale prescription drug distributor for which the license is sought is or will be in full compliance with all state drug, narcotic and poison laws, and Chapters 461 and 95, Hawaii Revised Statutes.

Date

Signature of Applicant

Print Name

Title

WHOLESALE DRUG DISTRIBUTOR INSPECTION FORM

(Keep for Reference)

| FACILITIES: | S | U |
|--|----------|----------|
| A. Facility's size and construction facilitates cleaning, maintenance and proper storage. | | |
| B. Storage areas provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions. | | |
| C. Quarantine area maintained for storage of outdated, damaged, deteriorated, misbranded, adulterated prescription drugs. | | |
| D. Facility is free from infestation from insects, rodents, birds and vermin of any kind. | | |
| SECURITY: | | |
| A. Facility is secured from unauthorized entry; only authorized personnel are allowed into prescription drug area. | | |
| B. Access from outside premises is kept to a minimum. | | |
| C. Outside perimeter is well lighted. | | |
| D. Facility is equipped with alarm system. | | |
| E. Facility is equipped with security system to provide protection from theft and diversion. | | |
| STORAGE: | | |
| A. Prescription drugs stored at appropriate temperature and conditions as defined in an official compendium. | | |
| B. Firm is equipped with appropriate manual, electromechanical or electronic temperature and humidity recording equipment, devices, logs. | | |
| RETURNED OR DAMAGED DRUGS: | | |
| A. Damaged, outdated, deteriorated, misbranded or adulterated drugs are physically separated from other prescription drugs. | | |
| EXAMINATION OF MATERIALS: | | |
| A. All outgoing and incoming merchandise is examined for damage and accuracy. | | |
| RECORD KEEPING: Records kept at the firm indicate the following: | | |
| A. Source of drugs, name and principal address of seller or transferor, and address from which drugs were shipped. | | |
| B. Identify and quantity of drugs received and distributed/disposed, date of receipt and distribution/disposal. | | |
| C. Records are stored at the firm or are easily retrievable by computer. Records are stored for five years. | | |
| RESPONSIBLE PERSONS: | | |
| A. Current list of officers, directors, managers, and other personnel in charge of wholesale distribution, storage, and handling of prescription drugs is maintained at the firm. | | |
| B. Description of duties and qualifications of personnel is maintained at the firm. | | |
| SALVATION AND REPROCESSING: | | |
| A. Salvaging and reprocessing operation in compliance with 21 CFR 207, 210, 211. | | |
| WRITTEN POLICIES AND PROCEDURES: | | |
| A. Firm established and follows written policies and procedures for the receipt, security, storage, inventory, and distribution of prescription drugs. | | |
| B. Firm has policies for identifying, recording and reporting losses or thefts and correcting errors in inventories. | | |
| C. Firm has a procedure where oldest stock is distributed first. | | |
| D. Firm has a procedure for handling recalls/withdrawals of prescription drugs. | | |
| E. Firm has a procedure for handling return of outdated prescription drugs; segregation and written documentation of disposal. | | |
| F. Procedure for preparation, protection and proper handling of any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster or emergencies. | | |
| COMMENTS: | | |